

Twenty-five years of experience with out-center hemodialysis

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Background. Out-center hemodialysis (HD) offers patients a better quality of life, a greater independence, and a better rehabilitation opportunity. A lower mortality than with other modalities of dialysis has been reported. In addition, in France the charges paid depend on the modality of dialysis, out-center HD being the less expensive, and savings are also accomplished through fewer patient transports, which are additionally reimbursed. We present a 25-year experience of out-center HD.

Methods. We retrospectively studied the clinical records of 471 patients treated between 1974 and 1997 in a single nonprofit organization operating regional home HD (H-HD) and facilities for self-care HD (SC-HD). Survival results were analyzed according to: (a) causes of end-stage renal disease, (b) age at the start of HD, (c) period of start of HD, (d) modality of HD (H-HD, SC-HD), and (e) a subgroup of 174 patients defined at risk because they were contraindicated for transplantation.

Results. The mean age at the start of HD increased from 31.2 ± 9.7 (mean \pm SD) years in 1974 to 52.6 ± 13.5 years in 1997. Causes of the end of treatment were: (a) transplantation (63%), (b) transfer (20%), and (c) death (17%). The overall survival was 90% at 5 years, 77% at 10 years, 62% at 15 years, and 45% at 20 years, and, for the group at risk, 78%, 62%, 46%, and 31%, respectively. Cox proportional hazard analyses showed that risk factors were older age, diabetes, and renal vascular diseases.

Conclusion. If adequate choice is given, out-center HD offers a reliable and safe modality of dialysis with better survival results than survival in full-care in-center HD. In addition, out-center HD ensures a striking financial benefit as compared with the higher costs if the same patients were treated with full-care in-center HD. These modalities should be encouraged for all HD patients who are able to be treated by out-center modalities.

The development of dialysis modalities is dependent on economic resources. At the start of chronic treatment by dialysis in the 1960s, the capacity to receive all dialysis

patients in hospital centers was restricted, and home hemodialysis (H-HD) rapidly developed. Thereafter, the number of facilities increased, and the enthusiasm for H-HD treatment diminished despite reports of a lower mortality rate than in full-care center HD or peritoneal dialysis (PD) treatment [1–3], and despite the better quality of life and the greater independence and rehabilitation opportunity offered by H-HD to end-stage renal disease (ESRD) patients [4, 5]. Since 1984, self-care HD (SC-HD) units were developed as another alternative of the out-center HD, answering requirements of autonomous patients who did not have the possibility to be treated at home. The price of reimbursement of HD in France depends on the modality of treatment, with out-center HD (H-HD and SC-HD) being less expensive. The actual health policy requires a better control of expenses while keeping the best quality of health care. Nowadays, it is important to clearly define at the start of dialysis which modality is most suitable and which could offer the individual patient a better chance of survival. In ESRD chronic treatment, an analysis of survival is the best method to estimate the long-term results.

The “Association pour l'Utilisation du Rein Artificiel à Lyon” (A.U.R.A.L.) was created in 1974 to develop out-center dialysis treatment in the Rhône-Alps area (a total population of 5.35 million inhabitants) situated in the southeast section of France. In this article, the two out-center HD modalities that were used are described: H-HD and SC-HD. Our survival results are analyzed, and found to be better than the overall survival observed in center facilities in Europe [6, 7], Japan [8] and the United States [9]. Finally, the financial aspects are discussed, with a comparison between the costs of out-center HD and the costs in hospital centers in France.

Key words: dialysis modalities, home hemodialysis, self-care hemodialysis, end-stage renal disease, renal replacement therapy.

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METHODS

Patients

From January 1974 to December 1997, 654 patients were admitted in our training center, 102 patients for PD and 552 for out-center HD (H-HD or SC-HD). Be-

fore 1991, patients were treated by peritoneal dialysis (PD) in our units solely when HD was contraindicated. Therefore, to avoid a bias in patient selection, we did not include patients treated by PD in this analysis. Moreover, only new HD patients who were treated at least three months in our facilities were included. To avoid interferences of other modalities of ESRD treatment and to specifically study the quality of HD treatment offered in A.U.R.A.L., patients coming from other centers or other modalities of dialysis or who returned to dialysis after transplantation failure were excluded. Therefore, the survival analyses concerned 471 patients [mean age at the start of HD 43.5 ± 14.2 years (ranges 18.0 to 78.0), 132 females and 339 males] who were treated in out-center HD modalities (H-HD, SC-HD) and who started chronic HD in our facilities.

Definition of dialysis modalities

In France, the out-center HD is accomplished either by H-HD or SC-HD, the selection being done at the start of the training.

For H-HD, patients and assistants (often the spouses) were trained for two to four months and then were settled at home. Once at home, the patients made quarterly medical visits to the training center.

The SC-HD was applied in facilities out of the full-care center HD. Patients were trained during two to four months until reaching autonomy and were then settled in self-care facilities. In our structures, the organization of the SC-HD gave the possibility of patients to keep their autonomy, have a personal machine for each patient that was not used by the other patients, and to choose the best schedule for the HD session that was adapted to their activities, either in the morning or in the evening. A nurse was present during all of the sessions in order to help patients if necessary. The physician visited these units monthly, and the patients had quarterly medical visits in the training center.

The reliability of the machines and the water treatment were inspected by technicians at regular intervals both at home and in the self-care facilities. Patients were able call the training center and discuss any problem that appeared during the dialysis session with a nurse, a physician, or a technician. If the problem seemed to be important, the session could be performed in the training center. Availability of the medical and technical teams was very important in the success of the treatment and helped to ensure good results.

Dialysis policy

The frequency of dialysis was three times per week, and the session length was four to six hours, with a blood flow between 250 and 350 ml/min and a dialyzate flow at 500 ml/min. Generally, blood access was an arteriovenous fistula and exceptionally an arteriovenous graft.

Acetate buffer has been replaced by bicarbonate since 1990, and the use of unmodified cellulosic membrane was stopped in 1988, replaced by modified cellulosic or synthetic high-flux membrane. Reuse was not performed. Erythropoietin was introduced in 1992.

Calculations

Our data registry includes age, gender, causes of ESRD, presence of diabetes, modalities of dialysis, date of the start of dialysis in A.U.R.A.L., date of the end of dialysis in A.U.R.A.L., outcome of patients, and the causes of death.

The survival study started at the entry in our training center and stopped at the end of this treatment in our structures either by death, transplantation, or transfer, and was stopped on December 31, 1997, for patients remaining treated in our facilities. The annual gross mortality rate (GMR) was calculated as the number of deaths divided by half the number of patients alive on January 1 plus half the number alive on December 31 of each year.

Survival curves were analyzed for overall patients treated in A.U.R.A.L. Results were also analyzed according to the causes of ESRD. Patients were categorized according to the HD start age: 18 to 34 years (136 patients), 35 to 44 years (107 patients), 45 to 54 years (111 patients), 55 to 64 years (87 patients), and ≥ 65 years (30 patients) with a comparison between these groups. Patients were also categorized in chronological cohorts according to the period of the start of HD, and survival was analyzed according to the following cohorts: period 1974 to 1980 (78 patients), period 1981 to 1985 (108 patients), period 1986 to 1990 (121 patients), and period 1991 to 1997 (164 patients). The survival data were also analyzed according to the modalities of dialysis, that is, H-HD and SC-HD.

To analyze the survival results without the power impact of withdrawal by transplantation or by transfer to other facilities, we selected a group of 174 patients, age 49.5 ± 14.2 years, who were continuously followed in our facilities, including only patients still dialyzed in A.U.R.A.L. and those deceased. This group of 174 patients could be considered at risk because they were not accepted for transplantation, especially because of their old age and/or medical contraindication.

Results of survival were then compared with survival in center HD reported in Europe [6, 7], Japan [8], and the United States [9].

Statistics

Data were managed on a "Power Macintosh." Database software and statistical calculations including survival curves were done using Statview F-4.5 software (Abacus Concepts Incorporated, Berkeley, CA, USA). Results were presented as mean \pm SD. Analysis of variance was used to compare the characteristics between

Table 1. Characteristics of new patients and gross mortality rate (GMR)

Year	New pts	Diabetic	Sex M/F	H-HD/SC-HD	Age at start	Death	Transplant	Transfer	GMR
1974	9	0	9/0	9/0	31.2 ± 9.7	0	0	0	0.000
1975	8	0	6/2	8/0	32.3 ± 8.2	0	1	0	0.000
1976	14	1	11/3	14/0	37.1 ± 10.3	0	2	0	0.000
1977	15	2	11/4	15/0	37.4 ± 9.8	3	2	1	0.092
1978	10	0	9/1	10/0	38.4 ± 12.0	2	1	4	0.053
1979	10	2	7/3	10/0	42.4 ± 10.0	0	5	5	0.000
1980	12	0	9/3	12/0	38.7 ± 13.5	0	2	1	0.000
1981	14	1	10/4	14/0	37.6 ± 13.1	1	2	5	0.019
1982	20	0	13/7	20/0	39.7 ± 10.6	2	10	5	0.035
1983	23	1	20/3	23/0	43.2 ± 12.9	2	4	2	0.031
1984	33	1	22/11	12/21	41.9 ± 16.6	3	5	4	0.036
1985	18	0	15/3	9/9	38.2 ± 15.2	1	6	2	0.010
1986	29	0	16/13	15/14	44.6 ± 13.4	2	10	1	0.018
1987	22	0	13/9	11/11	47.6 ± 11.7	1	14	4	0.008
1988	25	3	20/5	10/15	46.9 ± 13.3	2	15	2	0.016
1989	25	0	22/3	7/18	42.6 ± 14.3	4	22	2	0.032
1990	20	0	15/5	6/14	47.6 ± 17.4	4	19	7	0.034
1991	20	2	13/7	4/16	39.9 ± 17.0	0	15	5	0.000
1992	19	0	12/7	3/16	49.6 ± 12.0	3	15	3	0.027
1993	24	1	14/10	3/21	43.3 ± 13.7	2	11	3	0.017
1994	27	1	21/6	4/23	44.7 ± 15.9	0	19	4	0.000
1995	25	1	19/6	5/20	46.1 ± 13.7	10	15	3	0.081
1996	29	4	19/10	5/24	49.4 ± 14.1	6	15	5	0.048
1997	20	3	13/7	2/18	52.6 ± 13.5	12	14	5	0.100
Total	471	23	339/132			60	224	73	

The number of new patients (pts), the number of diabetics, the sex ratio (male/female), the ratio of home hemodialysis (H-HD)/self-care hemodialysis (SC-HD), the age at the start of hemodialysis treatment, the causes of the end of the treatment in A.U.R.A.L. (death, transplantation, or transfer), and the gross mortality rate (GMR).

the groups according to the outcome of patients. Survival curves were drawn using the Kaplan–Meier method, and a comparison between survival curves was analyzed using log-rank test. Cox proportional hazard analysis was performed to determine the relative risk (hazard ratio) of each studied covariate: sex (female as reference), causes of ESRD (CGN as reference), age at the start of HD (group of age ≤34 years as reference), period of the start of HD (period 1986 to 1990 as reference), and modality of dialysis (SC-HD as reference).

RESULTS

A 1994 report showed that in the Rhône-Alps area, 3213 ESRD patients were treated on December 31, 1993, which was equivalent to 573 per million population: 1708 patients were undergoing maintenance dialysis (319 per million population), and 1505 patients had a functioning transplant [10]. During the year 1993, 406 new patients started dialysis (75.8 per million population). Dialysis patients were treated by PD (12%), SC-HD (16.6%), and H-HD (7%) and by full-care in-center HD (64.4%).

Table 1 shows the characteristics of incident patients from 1974 to 1997, the distribution between H-HD and SC-HD, the causes of the end of the treatment in our center (death, transplantation, transfer), and the GMR. The mean age at the start of HD treatment increased from 31.2 ± 9.7 years in 1974 to 52.6 ± 13.5 years in

1997. Diabetes was the cause of ESRD in only 5% of the cases, renal vascular diseases in 12%, and chronic glomerulonephritis (CGN) in 45%. The overall other causes, which included interstitial nephritis, polycystic kidney disease, and other known causes, accounted for 34%, and the unknown causes accounted for 4%. Forty-nine percent of the patients were treated at home and 51% in self-care facilities. Since 1984, H-HD decreased dramatically, and on 1997, it represented only 10% of the new patients settled for out-center HD.

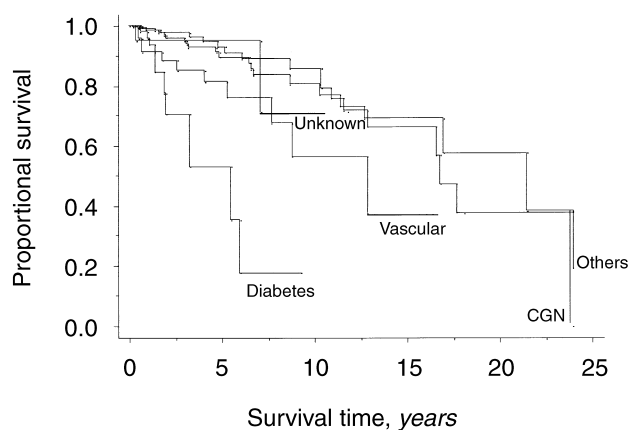
The outcome of the patients in our facilities was distributed between transplantation (63%), transfer (to center structures or to other regions, 20%), and death (17%). The waiting time in dialysis before transplantation was 3.0 ± 2.8 years. Causes of death were cardiovascular diseases (50%), infections (12%), cancer (10%), cerebrovascular diseases (4%), and miscellaneous (24%).

The GMR was 2.74 ± 2.94% (ranges 0 to 10%; median 1.85%). However, the GMR increased progressively since 1995 and reached 10% in 1997. The cumulative survival of the overall patients was 90% at 5 years, 77% at 10 years, 62% at 15 years, and 45% at 20 years (Table 2). Figure 1 shows the survival curves according to the ESRD causes. Significant differences were observed between groups ($P < 0.0001$), with diabetes and renal vascular diseases having the worse results. Figure 2 shows curves according to the age at the start of HD with significant differences ($P < 0.0001$). However, no sig-

Table 2. Survival according to the age at the start of hemodialysis

	Age years					Total
	≤34	35–44	45–54	55–64	≥65	
Overall patients						
N patients	(136)	(107)	(111)	(87)	(30)	(471)
Survival						
5 years	0.98	0.93	0.85	0.83	0.72	0.90
10 years	0.89	0.83	0.82	0.64	0.49	0.77
15 years	0.89	0.75	0.59	0.44	—	0.62
20 years	0.75	0.50	—	—	—	0.45
Continuously followed group						
N patients	(28)	(28)	(46)	(47)	(25)	(174)
Survival						
5 years	0.92	0.73	0.71	0.75	0.81	0.78
10 years	0.79	0.50	0.67	0.55	0.51	0.62
15 years	0.79	0.41	0.46	0.36	—	0.46
20 years	0.65	0.29	0.33	—	—	0.31

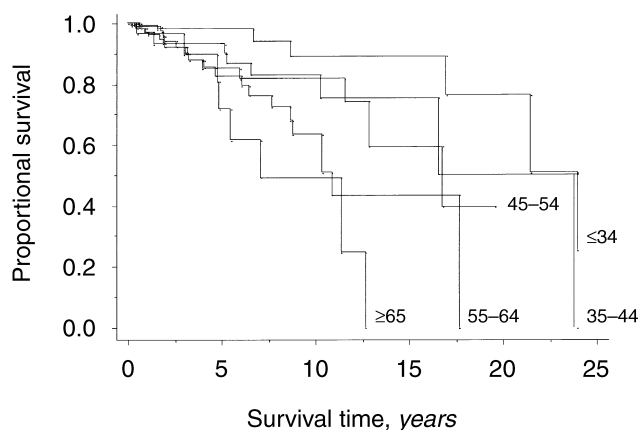
Results of survival at 5, 10, 15 and 20 years are shown for the group of overall patients and the group of patients continuously followed in our facilities. The number of patients enclosed in the survival analyses are in parentheses.



Number of patients included in survival analyses

	Start	Survival, years			
		5	10	15	20
CGN	212	49	27	11	2
Others	160	56	25	14	4
Unknown	20	4	3	—	—
Vascular	56	18	5	1	—
Diabetes	23	3	—	—	—

Fig. 1. Survival curves drawn as Kaplan-Meier method in groups according to causes of ESRD. Diabetes and vascular causes have the poorer prognosis.



Number of patients included in survival analyses

Age, years	Start	Survival, years			
		5	10	15	20
18–34	136	34	18	14	4
35–44	107	31	12	4	1
45–54	111	27	14	6	1
55–64	87	29	13	2	—
≥65	30	9	3	—	—

Fig. 2. Survival curves drawn as Kaplan-Meier method in groups according to the age at the start of hemodialysis, with significant differences.

nificant differences were found according to the periods of the start of HD between 1974 and 1997 (data not shown). Survival was comparable between H-HD and SC-HD (data not shown). The cumulative survival for the subgroup of 174 patients continuously followed in A.U.R.A.L., who were neither considered for transplantation nor transferred, and including 24% of high risk etiologies (9% diabetes and 15% renal vascular dis-

eases), was 78% at 5 years, 62% at 10 years, 46% at 15 years, and 31% at 20 years (Table 2).

The results of Cox hazard analyses are summarized in Table 3 for the group of overall patients. The results were influenced by age. There was no marked sex difference in survival. Diabetes and renal vascular diseases had the significantly worse prognosis. The period of the start of HD and the modality of HD did not influence the prognosis.

Table 3. Results of Cox hazard analyses

Covariates	N patients	% Pts	Hazard risk	95% CI	P value
Sex					
Female	132	28	1		
Male	339	72	1.398	0.717–2.727	0.326
Cause of ESRD					
CGN	212	45	1		
Other	160	34	1.205	0.619–2.345	0.5838
Unknown	20	4	1.364	0.289–6.432	0.6948
Vascular	56	12	2.558	1.187–5.513	0.0165
Diabetes	23	5	7.009	2.801–17.542	<0.0001
Age at start of HD					
≤34 years	136	29	1		
35–44 years	107	23	2.884	1.121–7.418	0.0280
45–54 years	111	24	2.744	1.037–7.259	0.0420
55–64 years	87	18	5.462	2.029–14.707	0.0008
≥65 years	30	6	7.715	2.435–24.437	0.0005
Period of start of HD					
1974–1980	78	16	1.040	0.395–2.740	0.9365
1981–1985	108	23	1.325	0.593–2.961	0.4927
1986–1990	121	26	1		
1991–1997	164	35	1.700	0.653–4.424	0.2770
Modality of dialysis					
SC-HD	240	51	1		
H-HD	231	49	1.535	0.718–3.282	0.2694

A total group of 471 patients is shown. Abbreviations are: 95% CI, confidence intervals; Pts, patients; ESRD, end-stage renal disease; CGN, chronic glomerulonephritis; HD, hemodialysis; SC-HD, self-care hemodialysis; H-HD, home hemodialysis. Significantly different from reference, $P < 0.05$.

DISCUSSION

Few data are yet available on survival in specific out-center HD populations. H-HD was estimated to be only 0.1% of the overall dialyzed population in Japan [11] and 1% of the overall dialyzed population in the United States [1].

The annual report of the European registry (EDTA) [12] showed that on December 31, 1995, 33,713 patients were treated in France for ESRD (580 per million population), with 61.7% of patients treated by dialysis. In the Rhône-Alpes area [10], the number of ESRD patients treated on December 31, 1993, is similar to the French national prevalence. However, only 53% were undergoing maintenance dialysis, and 23.6% of the dialyzed population were undergoing an out-center HD procedure (H-HD, SC-HD). Four nonprofit organizations deliver PD and out-center HD in the Rhône-Alps area, A.U.R.A.L. being the oldest, with 25 years of experience in the specific out-center dialysis treatment.

Since 1984, the year of the opening of the first self-care facility in our region, the home-HD dramatically decreased, and presently only 10% of the new out-center HD patients are choosing the H-HD. Indeed, the SC-HD in our structures is presented as a real alternative of H-HD, essentially to autonomous patients who do not have the possibility of being treated at home. Each patient has his personal machine that is not used by the other patients. In addition, patients have the possibility of choosing a timing of the HD session that is adapted to their activities, in the morning or in the evening after

work. Nevertheless, 49% of overall patients were treated in H-HD and 51% in self-care facilities, and the survival results were comparable in these two groups, suggesting that the choice of the method depends rather on personal preference than on the medical condition of the patients.

This study showed excellent survival results. The mean age at the start of HD increased progressively from 31.2 ± 9.7 years in 1974 to 52.6 ± 13.5 years in 1997, and the GMR also increased progressively, reaching 10% in 1997. This more pronounced GMR could be explained by the older age of patients currently dialyzed and the accumulation of years of dialysis. Diabetes and renal vascular diseases had significant differences of survival when compared with CGN and with the other causes of ESRD, with worse results being observed for diabetic patients. Death was registered in 17% of the overall outcome. Cardiovascular diseases accounted for 50% of the causes of the fatal evolution, which was similar to other published studies [8, 13]. Infections were the causes of death in only 12% of the cases, in part because the absence of the nosocomial infection risk, which is more prevalent in hospital centers. In a United States Renal Data System report, infection accounts for almost a quarter of all deaths in the 20- to 44-year age group, 17% and 14% of deaths in the 45- to 64-year and 65-year and older age groups, respectively [9].

In this study, transplantation represented 63% of the overall outcome, confirming our policy of encouraging transplantation when it is possible. The high rate of transplantation associated with the transfer of patients to other locations complicated data collection and analyses. To

analyze the survival results without the power impact of withdrawal by transplantation or by transfer, we selected a group of 174 patients who were continuously followed in A.U.R.A.L. These patients did not have the possibility of being transplanted because of their old age and/or because of medical contraindication. Although this group represented patients at risk, their cumulative survival was also satisfactory.

The comparison of survival results between different centers should be used with caution because there are regional differences of life expectancy in the general population. Varieties in dialysis procedures and comorbid factors should also be taken into account. Finally, the withdrawal rate for kidney transplantation fluctuated. Hull and Parker reported that countries with high rates of transplantation will probably have the highest dialysis-related mortality as long as dialysis is a less sufficient form of renal replacement therapy and younger, more healthy patients are removed to transplantation [14]. Our results seem to be better than those reported by Okinawa, by the United States Renal Data System report, and by Tassin [6–9], and the GMR was lower in this study than in other published reports [14]. In a preliminary analysis reflection, we could explain the good results of the cumulative survival in our dialyzed population by the impact of patients' selection for the out-center HD (H-HD, SC-HD). This population was younger and had fewer comorbid factors; essentially they had less association with diabetes, and represented a smaller sample size than the Okinawa [8] and United States Renal Data System [9] patients, whereas our general population was comparable with the Tassin population for demography and age [6]. However, the results of our study seem to be better when we compared the same groups of age and the nondiabetes groups, even with the group of 174 patients at risk [8, 9, 15], and despite the higher rate of transplantation in A.U.R.A.L. patients than in the group from Okinawa, arguing for the beneficial effect of the out-center treatment on the prognosis, and confirming the results of the study previously reported by Woods et al [1] from the United States. Those authors showed a striking reduction in mortality for patients selected for treatment by H-HD compared with patients treated in center HD, and statistical adjustment for comorbid conditions in addition to age, sex, race, and diabetes explained only a small amount of the lower mortality with H-HD [1]. Indeed, patients treated in out-center structures could be more motivated and more compliant with medication, diet, and dialysis prescription.

In addition to these satisfactory survival results, the out-center treatment ensures a striking financial benefit as compared with higher costs if these patients were treated in center structures. In France, according to multiple administrative adjustments, the reimbursement of

HD depends on the modality of treatment, with the out-center HD (H-HD, SC-HD) being the less reimbursed [16]. H-HD and SC-HD are 50% less expensive than full-care in center HD [16, 17]. An analysis of the annual costs of dialysis treatments performed in France in 1994 estimated the expenditure per patient at \$80,000 for the full-care in-center HD, \$50,000 for the SC-HD, \$42,000 for the H-HD, and \$42,000 for continuous ambulatory PD (all in U.S. dollars) [16]. In fact, no staff is needed for H-HD, and fewer staff are needed in the self-care facilities than in full-care center HD. Moreover, the geographic distribution of the centers in France is restricted to the great urban centers, and patients sometimes travel for long distances between home and centers. In contrast, H-HD spares transport costs, and many self-care facilities were installed in the large and also in the small cities in order to reduce transport distance. The total cost of transport is additionally reimbursed in France, and patient transportation accounts for 12 to 18% of the total cost of HD therapy [16]. Therefore, it seems clear that social security could save money with H-HD and SC-HD.

In conclusion, the out-center HD represents a reliable and safe modality of treatment for ESRD patients if an adequate choice for the method of dialysis is done. Our overall survival results in out-center HD (H-HD, SC-HD) appear to be excellent and were higher than in other center structures. These better results could be related in part to the bias of selection of the patients, knowing also that better results occur in the group at risk. Indeed, the stronger motivation of the patients and the greater compliance to the treatment play a role. In addition, out-center HD ensures financial economies of the society, and these methods should be encouraged for all HD patients able to be treated by out-center modalities.

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